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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,656	10/09/2003	Sundeep Dugar	219002029600	2874

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/683,656

Applicant(s)

DUGAR, SUNDEEP

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/03/06 status inquiry.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-41 are pending.

2. ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 31, drawn to pyrrolodiazine/furanodiazine/thienodiazine compounds, classified in class 544, subclass 350+ depending on species election. If this group is elected, a further election of a single disclosed species is also required. Claims 1-10, 11-28, 33, 39-41 can be prosecuted with the elected compounds to the extend of the elected compounds i.e. $Z4=Z5=N$.
- II. Claims 29-30, drawn to pyrrolopyridine/furanopyridine/thienopyridine compounds, classified in class 546, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required. Claims 1-10, 11-28, 33, 39-41 can be prosecuted with the elected compounds to the extend of the elected compounds i.e. one of $Z4$ or $Z5$ is N .
- III. Claim 10 not encompassing groups I or II, drawn to piperazinyl-indole/benzofuran/benzothienyl compounds, classified in class 544, subclass various depending on species election. If this group is elected, a further election of a single disclosed species is also required. Claims 1-10, 11-28, 33, 39-41 can be prosecuted with the elected compounds to the extend of the elected compounds i.e. $Z4=Z5=CR1$, $Z1=N$, $l+k=4$.
- IV. Claims 1-9, 11-28, 3, 39-41 $Z1$ is $Cr1$, $l+k=4$, drawn to piperidiny-indole/benzofuran/benzothienyl compounds, classified in class 546, subclass various depending on species election. If this group is elected, a further election of a single disclosed species is also required. Claims 1-10, 11-28, 33, 39-41 can be prosecuted with the elected compounds to the extend of the elected compounds i.e. $Z4=Z5=CR1$, $Z1=CR5$, $l+k=4$.
- V. Claims 1-10, 11-28, 33, 39-41 drawn to remaining compounds not encompassed by groups I-IV, classified in class various, subclass various depending on species

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election. If this group is elected, a further election of a single disclosed species is also required. Further restriction may be required based on the species election.

VI. Claims 34-35, drawn to multiple active ingredient composition, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single combination composition with every component named. Further restriction may be required based on the species election.

VII. Claims 36-38, drawn to method of treating diseases, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disease/disorder and a single compound for treating the elected disorder is also required. Further restriction based on the species election may be required.

The inventions are independent or distinct, each from the other because:

Inventions Groups I-V compounds, differ in elements, chemical bonding and chemical property to such an extent that a reference anticipating any one of the groups I-V would not render the other groups obvious. Not only the search for each core is not co-extensive, art of record indicated that each "core" structure has different utility and the search for each core structure is not co-extensive of another core, i.e. pyridinylindolyl core has protein kinase inhibiting utility (see US 6,897,207); pyridinylfuranyl core has ACK1-enzyme modulating activity (see US 206/0046977). Extreme burden would be imposed on the office were restriction not made.

Inventions Group VI and groups I-V are independent and distinct because basis or patentability of a multiple component composition depends on the individual ingredient and their quantitative relationship which is not coextensive with the patentability of compound per se.

Inventions Groups I-V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating rheumatoid arthritis can be practiced with a material different product such as found in US 6,649,636, see col. 92, claim 18.

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Claims 1-9, 11-28, 33, 39-41 link inventions I-V. The restriction requirement of groups I-V the linked inventions is **subject to** the nonallowance of the linking claims, claims 1-9, 11-28, 33,39-41. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper

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restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the “reach-through” format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease. Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 22, 2006


Celia Chang
Primary Examiner
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